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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/692,023

10/22/2003

Arno Blau

SCHWP0183USA

8542

7590 11/23/2009  
RENNER, OTTO, BOISSELLE & SKLAR, LLP  
Nineteenth Floor  
1621 Euclid Avenue  
Cleveland, OH 44115-2191

EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/692,023 | <b>Applicant(s)</b><br>BLAU ET AL. |  |
|                              | <b>Examiner</b><br>DAVID COMSTOCK    | <b>Art Unit</b><br>3733            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-9 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertuch, Jr. (4,305,394).

Bertuch, Jr. disclose a system for positioning an implant 109 comprising a holding element, e.g., 23, 31, 55 and a guiding sleeve 13 (see, e.g., Figs. 1-7). The holding element and implant connect at a threaded interface and both comprise a conically tapered section (i.e. the bottom of the threaded hole in the implant and the end of the threaded connection element of the holding element). The guiding sleeve includes entry and exit openings having rims. The holding element is configured to rotate and translate within the sleeve (as by rotation within the threads 37, cf. Figs. 4 and 5). The holding element has clearly been introduced into the sleeve, but is also removable therefrom by unthreading the threads 25 from the end sleeve 21 and by unthreading the holding element from portion 39.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertuch, Jr. (4,305,394) in view of Bertin (5,320,625).

Bertuch, Jr. discloses the claimed invention except for the navigational element. Bertin also discloses a system for positioning an implant 52 comprising a holding element 82, a guiding sleeve 96 and a navigational element 102, 104 on the sleeve (see Figs. 4 and 5). The navigational element allows the device to be positioned accurately to ensure an accurate and effective surgical procedure (see, e.g., col. 11, lines 25-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant positioning system of Bertuch, Jr. with a navigational element, in view of Bertin, in order to allow the device to be positioned accurately to ensure an accurate and effective surgical procedure. A sliding element, e.g. 65 (which slides within hole 67), is connected to the guiding sleeve via flange 41 and flange support 39. It is noted that the navigational element as taught by Bertin would be connected to the outer structure, i.e., the guiding sleeve. Even if the device did not set forth sliding elements such as element 65, it would have been further obvious to provide the navigational element on a sliding portion or on any of numerous other known adjustment mechanisms, since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

***Allowable Subject Matter***

Claim 10 is allowable over the prior art of record.

***Response to Arguments***

Applicant's arguments filed 20 July 2009 have been reconsidered but they are not persuasive.

It is noted that the rejection refers to the figures which show various embodiments of handles that can be considered as the claimed "tensioning device." For example, handle 7 is at the end of a long lever arm and allows for significant torque which acts on the implant and portions of the device attached thereto, such as the holding element. Moreover, other handle embodiments such as 15, 75 and 89 are also capable of performing a tensioning function. In addition, the element in Bertin is specifically designed with a specific configuration that is at least capable of being detected or tracked by various known navigation systems including, for example, direct visualization systems, 3D optical scanners, coordinate measuring machines and imaging systems such as "x-ray". The pair of arms shown in the figures set forth in the rejection constitute markers. The limitation "specifically designed for" is simply another way of stating intended use. However, since the prior art is designed with a specific configuration that is capable of being tracked, it satisfies the claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the

Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733